

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TERESITA SAYERS**

I. PREAMBLE

Teresita Sayers ("Sayers") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS"). All terms and obligations of this CIA shall attach to any and all entities that submit claims for reimbursement to the Federal health care programs, in which Sayers has or gains an ownership or management interest during the term of this CIA (such entities shall hereinafter be referred to individually and collectively as "Sayers Entities"). This CIA is intended to ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs") by Sayers, all Sayers Entities, and their employees, physicians and other health care professionals, as well as all third parties with whom Sayers or any Sayers Entity may choose to engage to act as billing or coding agents or consultants. Sayers's compliance with the terms and conditions in this CIA shall constitute an element of Sayers's present responsibility to participate in the Federal health care programs. Contemporaneously with this CIA, Sayers is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

For the purposes of this CIA, an "ownership or management interest" shall mean a direct or indirect ownership or control interest (as defined in 42 U.S.C. §1320a-3(a)(3)), or the position of officer, director, agent, or managing employee (as defined in 42 U.S.C. § 1320a-5(b)). At the time of execution of this CIA, Sayers represents that New Age Medical Supply, Inc. is the only entity that submits claims for reimbursement to the Federal health care programs in which Sayers has such an ownership or management

interest. Sayers is obligated under this CIA to ensure that all Sayers Entities meet and comply with all obligations of this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Sayers and the Sayers Entities under this CIA shall be five (5) years (unless otherwise specified) from the date on which the final signature of this CIA is acquired. The “effective date” of this CIA will be the date on which the final signature of this CIA is acquired, thereby executing this CIA, or, for any entity becoming a “Sayers Entity” after the execution of this CIA, the date on which that entity becomes a Sayers Entity.

III. CORPORATE INTEGRITY OBLIGATIONS

Sayers shall establish a compliance program that includes the following elements. Unless otherwise specified, the following requirements shall be implemented by Sayers and each Sayers Entity within 90 days of the effective date of this CIA.

A. Compliance Officer:

Sayers shall appoint an individual to serve as Compliance Officer, who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by all Sayers Entities to further their compliance objectives as well as for any reporting obligations created under this CIA. In the event the identity of the Compliance Officer changes during the term of this CIA, Sayers shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. Written Standards.

1. *Code of Conduct.* Sayers shall establish a Code of Conduct. The Code of Conduct shall be distributed to all employees, physicians, contractors and agents of Sayers and the Sayers Entities. Sayers and each Sayers Entity shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

- a. Sayers’s and the Sayers Entities’ commitment to full compliance with all statutes, regulations, and guidelines applicable to all Federal health care programs, including the commitment to prepare and submit accurate billings consistent with Federal health care program

regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;

b. Sayers's and the Sayers Entities' expectation that all of their employees, physicians, contractors and agents shall comply with all statutes, regulations, and guidelines applicable to the Federal health care programs and with the Sayers Entities' own policies and procedures (including the requirements of this CIA);

c. The requirement that all Sayers's and the Sayers Entities' employees, physicians, contractors and agents shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of the respective Sayers Entity's own Policies and Procedures;

d. The possible consequences to Sayers, the Sayers Entities' and to any employee, physician, contractor or agent of failure to comply with all statutes, regulations, and guidelines applicable to the Federal health care programs and with the Sayers Entities' Policies and Procedures or of failure to report such non-compliance; and

e. The right of all employees, physicians, contractors and agents to use the Confidential Disclosure Program, as well as Sayers's and the Sayers Entities' commitment to confidentiality and non-retaliation with respect to disclosures.

Each employee, physician, contractor and agent of Sayers and of each Sayers Entity shall certify, in writing, that he or she has received, read, understands, and will abide by the Code of Conduct. New employees, physicians, contractors and agents shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment or contract, or within ninety (90) days of the effective date of the CIA, whichever is later.

Sayers will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Employees, physicians, contractors and agents of Sayers and the Sayers Entities shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. *Policies and Procedures.* Sayers shall develop and initiate implementation of written Policies and Procedures regarding the operation of the Sayers's

compliance program and compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. At a minimum, the Policies and Procedures shall specifically address proper billing to the Federal health care programs for services provided under a physician's supervision. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to management through the Confidential Disclosure Program required by section III.E. Sayers shall assess and update as necessary the Policies and Procedures as appropriate and at least annually. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

The relevant portions of the Policies and Procedures for each Sayers Entity shall be distributed to all appropriate employees, physicians, contractors and agents of Sayers or any Sayers Entity. Compliance staff or supervisors should be available to explain any and all Policies and Procedures.

C. Training and Education.

1. *General Training.* Sayers shall provide at least two (2) hours of training regarding compliance obligations and the compliance program to each employee, physician, contractor and agent of Sayers and the Sayers Entities. This general training shall explain the:

- a. Corporate Integrity Agreement requirements;
- b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
- c. Code of Conduct.

Persons providing the general training must be knowledgeable on the subject area. The training materials used in the general training shall be made available to the OIG, upon request.

New employees, physicians, contractors and agents shall receive the general training described above within thirty (30) days of the beginning of their employment or contract, or within ninety (90) days after the effective date of this CIA, whichever is later. Each year, every employee, physician, contractor and agent shall receive such general training on an annual basis.

2. *Specific Training.* Sayers shall provide at least four (4) hours of training in addition to the general training required above to each employee, physician, contractor

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or agent who is involved directly or indirectly in the delivery of patient care and/or in the preparation or submission of claims for reimbursement for such care (including, but not limited to, coding and billing) for any Federal health care program. This training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;
- b. policies, procedures and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement rules and statutes;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

Persons providing the specific training must be knowledgeable about the subject area. The training materials used in the specific training shall be made available to OIG, upon request.

All new employees, physicians, contractors and agents who will be involved directly or indirectly in the delivery of patient care and/or in the preparation or submission of claims for reimbursement for such care (including, but not limited to, coding and billing) for any Federal health care program shall receive this specific training within thirty (30) days of the beginning of their employment or contract or within ninety (90) days of the effective date of this CIA, whichever is later. If a new employee, physician, contractor or agent of Sayers or a Sayers Entity has any responsibility for the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, an employee, physician, contractor or agent of Sayers or that Sayers Entity who has completed the training shall review all of the untrained person's work regarding the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes.

Every employee, physician, contractor and agent of Sayers and each Sayers Entity who is involved directly or indirectly in the delivery of patient care and/or in the preparation or submission of claims for reimbursement for such care (including, but not limited to, coding and billing) for any Federal health care program shall receive such specific training on an annual basis.

3. *Certification.* Each employee, physician, contractor and agent of Sayers and each Sayers Entity shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with the training materials used. These shall be made available to OIG upon request.

D. Review Procedures.

Sayers shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist Sayers in determining the adequacy of the billing and compliance practices of Sayers and each Sayers Entity pursuant to this CIA. Such review procedures shall be performed annually and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which the retaining Sayers Entity seeks reimbursement. The Independent Review Organization must be retained within (90) days of the effective date of this CIA to conduct the audit of the first year.

The Independent Review Organization(s) shall be retained by Sayers to conduct two separate engagements. One engagement will analyze Sayers's and the Sayers Entities' billing to the Federal health care programs to assist Sayers and the Sayers Entities and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance (the "billing engagement"). The second engagement will determine whether Sayers and the Sayers Entities are in compliance with this CIA (the "compliance engagement").

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers selection and shall be selected by using the OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html".

Each annual billing engagement analysis shall include the following components in its methodology:

- a. Billing Engagement Objective: A statement stating clearly the objective intended to be achieved by the billing engagement and the

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procedure or combination of procedures that will be applied to achieve the objective.

b. **Billing Engagement Population:** The identity of the population, which is the group about which information is needed, and an explanation of the methodology used to develop the population and the basis for this determination.

c. **Sources of Data:** A full description of the source of the information upon which the billing engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.

d. **Sampling Unit:** A definition of the sampling unit, which is any of the designated elements that comprise the population of interest.

e. **Sampling Frame:** The identity of the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The billing engagement shall provide:

a. Findings regarding the retaining Sayers Entity's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);

b. Findings regarding whether the retaining Sayers Entity is submitting accurate claims for services billed to the Federal health care programs.

c. Findings regarding the retaining Sayers Entity's procedures to correct inaccurate billings or codings to the Federal health care programs;

d. Findings regarding whether the retaining Sayers Entity's programs, policies, operations, and procedures comply with the applicable statutes, regulations and other requirements the Federal health care programs from which the retaining Sayers Entity seeks reimbursement; and

e. Findings regarding the steps the retaining Sayers Entity is taking to bring its operations into compliance or to correct problems identified by the audit.

A complete copy of each Independent Review Organization's billing engagements shall be included in the Annual Report to OIG for the year in which the engagement was conducted.

2. *Compliance Engagement.* The compliance engagement shall provide an analysis of whether Sayers and the Sayers Entities' program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include a section by section analysis of the requirements of this CIA.

A complete copy of each Independent Review Organization's compliance engagement shall be included in the Annual Report to OIG for the year in which the engagement was conducted.

3. *Disclosure of Overpayments and Material Deficiencies.* If, as a result of these engagements or through any other means, Sayers or one of the Sayers Entities or the Independent Review Organization identifies any billing, coding or other policies, procedures and/or practices that result in an overpayment (as defined below), Sayers or the appropriate Sayers Entity shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the deficiency or overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency from recurring. The notice to the payor shall include:

- a. A statement that the refund is being made pursuant to this CIA;
- b. A description of the complete circumstances surrounding the overpayment;
- c. The methodology by which the overpayment was determined;
- d. The amount of the overpayment;
- e. Any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date); and
- f. The provider identification number under which the repayment is being made.

If Sayers or any of the Sayers Entities determines an overpayment represents a material deficiency (as defined below), contemporaneous with Sayers's or the appropriate Sayers Entity's notification to the payor as provided above, Sayers or the appropriate Sayers Entity shall also notify OIG of:

- a. A complete description of the material deficiency;
- b. The amount of overpayment due to the material deficiency;
- c. The appropriate Sayers Entity's action(s) to correct and prevent such material deficiency from recurring;
- d. The payor's name, address, and contact person where the overpayment was sent;
- e. The date of the check and identification number (or electronic transaction number) on which the overpayment was repaid.

For purposes of this CIA, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to any Federal health care program; (ii) conduct or policies that clearly violate the Federal health care program statutes, regulations or directives issued by HCFA and/or its agents or the regulators or agents of any Federal health care program; or (iii) serious quality of care implications for Federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

4. *Verification/Validation.* In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which Sayers or any Sayers Entity is complying with its obligations under this CIA, Sayers and the appropriate Sayers Entity agree to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

E. Confidential Disclosure Program.

Sayers shall develop a Confidential Disclosure Program, which must include measures to enable employees, physicians, contractors and agents of Sayers and all Sayers Entities to disclose to the Compliance Officer any identified issues or questions associated with any Sayers Entity's policies, practices or procedures with respect to a Federal health care program, believed by the individual to be inappropriate.

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the

individual reporting the alleged misconduct. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides an opportunity for taking corrective action, Sayers or the Sayers Entity shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements.* Sayers and the Sayers Entities shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Sayers and the Sayers Entities shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.arnet.gov/epl>) and the HHS/OIG Cumulative Sanction Report (available through the Internet at <http://www.dhhs.gov/progorg/oig>) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within ninety (90) days of the effective date of this CIA, Sayers and each Sayers Entity will review its lists of current employees and contractors against the Exclusion Lists. Thereafter, Sayers and the Sayers Entities will review the list once semi-annually. If Sayers or the Sayers Entities have notice that an employee, agent, or physician has become an Ineligible Person, Sayers and the Sayers Entities will remove such person from responsibility for, or involvement with, Sayers and the Sayers Entities' business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal

funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Sayers or any Sayers Entity has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with Sayers or the Sayers Entity, within 10 days of receiving such notice Sayers or the Sayers Entity will remove such individual from responsibility for, or involvement with, Sayers's and the Sayers Entities' business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

G. Notification of Proceedings.

Within 30 days of discovering any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Sayers or any Sayers Entity has committed a crime or has engaged in fraudulent activities or any other knowing misconduct, Sayers or the appropriate Sayers Entity shall notify the OIG in writing of the investigation or legal proceeding. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Sayers or the appropriate Sayers Entity shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Credible evidence of misconduct.* If Sayers or any Sayers Entity discovers credible evidence of her or its own misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law concerning Sayers's or that Sayers Entity's practices relating to the Federal health care programs, then Sayers or the appropriate Sayers Entity shall promptly report the probable violation of law to OIG. Sayers or the appropriate Sayers Entity shall make this disclosure as soon as practicable, but not later than 15 days after becoming aware of the existence of the probable violation. Sayers's or the Sayers Entity's report to OIG shall include:

- a. The findings concerning the probable violation, including the nature and extent of the probable violation;
- b. Sayers's or the Sayers Entity's actions to correct such probable violation; and

- c. Any further steps it plans to take to address such probable violation and prevent it from recurring.

To the extent the misconduct involves an overpayment, the report shall include the information listed in section III.D.3 regarding material deficiencies.

2. *Inappropriate Billing.* If Sayers or any Sayers Entity discovers inappropriate or incorrect billing through means other than the Independent Review Organization's engagement, Sayers or that Sayers Entity shall follow procedures in section III.D.3 regarding overpayments and material deficiencies.

IV. NEW OPERATIONS

In the event that Sayers or any Sayers Entity purchases or establishes new business units after the effective date of the CIA or Sayers obtains an ownership or management interest in an entity (thus converting the entity into a Sayers Entity), Sayers or the Sayers Entity shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. If such a new business unit falls into the definition of a "Sayers Entity" (as described in the Preamble), then all obligations of this CIA that may be imposed upon such a new Sayers Entity shall be met in a timely manner as if the date of purchase or establishment of the new Sayers Entity were the effective date of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Reports.

Within one hundred and twenty (120) days after the effective date of this CIA, Sayers shall submit a written report to OIG summarizing the status of the implementation of the requirements of this CIA. This Implementation Report shall include:

1. The name, address, phone number and position description of the Compliance Officer required by section III.A;
2. A copy of each of the Code of Conduct required by section III.B.1;
3. The summary of the Policies and Procedures required by section III.B.2;
4. A description of the training programs required by section III.C including a description of the targeted audiences and a schedule of when the training sessions were held;
5. A certification by the Compliance Officer that:

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- a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all pertinent employees, physicians, contractors and agents;
 - b. all employees, physicians, contractors and agents have completed the Code of Conduct certification required by section III.B.1; and
 - c. all employees, physicians, contractors and agents have completed the training and executed the certification required by section III.C.
6. A description of the Confidential Disclosure Program required by section III.E;
 7. The identity of the Independent Review Organization(s) and the proposed start and completion date of the initial audits; and
 8. A summary of personnel actions taken pursuant to section III.F.

B. Annual Reports.

Sayers shall collectively submit to OIG an Annual Report with respect to the status and findings of Sayers' and the Sayers Entities' compliance activities.

The Annual Reports shall include:

1. Any change in the identity or position description of the Compliance Officer described in section III.A;
2. A certification by the Compliance Officer that:
 - a. all employees, physicians, contractors and agents have completed the annual Code of Conduct certification required by section III.B.1; and
 - b. all employees, physicians, contractors and agents have completed the training and executed the certification required by section III.C;
3. Notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);
4. A complete copy of the reports prepared pursuant to the Independent Review Organization's billing and compliance engagements, including a copy of the methodology used;
5. A report summarizing the results of the Independent Review Organizations' billing and compliance engagements;

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6. Sayers's or the Sayers Entities' response/corrective action plan(s) to any issues raised by the Independent Review Organization(s) and the status of such action(s);
7. A summary of material deficiencies reported throughout the course of the previous twelve (12) months pursuant to III.D.3 and III.H.
8. A report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Such report shall include the date on which the overpayment was remitted, and the contractor or entity to whom the remittance was made. Overpayment amounts should be identified by the recipient (i.e., Sayers or the specific Sayers Entity) and broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
9. A copy of the confidential disclosure logs required by section III.E;
10. A description of any personnel action (other than hiring) taken by Sayers or a Sayers Entity as a result of the obligations in section III.F;
11. A summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Sayers or any Sayers Entity has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;
12. A listing of all of Sayers's and all of the Sayers Entities' locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and 30 days after the date of execution of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury that: (1) Sayers and each Sayers Entity is in

compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

Sayers:

Teresita Sayers
836 Winding Brook Lane
Walnut, CA 91787
Phone 909.594.2025

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s), may examine Sayers's and/or any Sayers Entity's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) Sayers's and/or the Sayers Entity's compliance with the terms of this CIA; and (b) Sayers's and/or the Sayers Entity's compliance with the requirements of the Federal health care programs in which he or it participates. The documentation described above shall be made available by Sayers or the Sayers Entity to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized

representative(s) may interview any of the Sayers Entities' employees, physicians, contractors or agents who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee, physician, contractor or agent and OIG. Sayers agrees to assist OIG in contacting and arranging interviews with such employees, physicians, contractors and agents upon OIG's request. Employees may elect to be interviewed with or without a representative of Sayers or the Sayers Entity present.

VIII. DOCUMENT AND RECORD RETENTION

Sayers and each Sayers Entity shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, for six years from the date of execution of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify the Coordinating Compliance Officer prior to any release by OIG of information submitted by Sayers or any Sayers Entity pursuant to its obligations under this CIA and identified upon submission by Sayers or any Sayers Entity as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Sayers and the Sayers Entities shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Sayers and the Sayers Entities are expected to fully and timely comply with all of the obligations of this CIA. Sayers shall be responsible for his obligations and the obligations of any Sayers Entities.

A. Stipulated Penalties for Failure to Comply with Certain Obligations.

As a contractual remedy, Sayers and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions. The following provisions describe stipulated penalties to be imposed against Sayers based on the conduct of Sayers and the Sayers Entities.

1. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 90 days after the

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effective date of this CIA and concluding at the end of the term of this CIA, Sayers fails to have in place any of the following:

- a. A Compliance Officer;
- b. A written Code of Conduct;
- c. A written Policies and Procedures;
- e. A training program; and
- f. A Confidential Disclosure Program;

2. A Stipulated Penalty of \$2000 (which shall begin to accrue on the day after the date the obligation became due) for each day Sayers fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the failure to comply began) for each day Sayers or any Sayers Entity:

a. hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which Sayers or the Sayers Entity can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);

b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Sayers's or the Sayers Entity's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which Sayers or the Sayers Entity can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person); or

c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, Sayers's or the Sayers Entity's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10

days after Sayers or the Sayers Entity received notice of the relevant matter or after the resolution of the matter).

4. A Stipulated Penalty of \$1500 (which shall begin to accrue on the date Sayers or the Sayers Entity fails to grant access) for each day Sayers or any Sayers Entity fails to grant access to the information or documentation as required in section VII of this CIA.

5. A Stipulated Penalty of \$1000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to Sayers of the failure to comply) for each day Sayers or any Sayers Entity fails to comply fully and adequately with any obligation of this CIA. In its notice to Sayers, the OIG shall state the specific grounds for its determination that the Sayers or the Sayers Entity has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Sayers or a Sayers Entity has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Sayers by personal service or certified mail of (a) Sayers or the Sayers Entity's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, Sayers or the appropriate Sayers Entity shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event Sayers elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Sayers or the Sayers Entity cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.C.

2. *Timely Written Requests for Extensions.* Sayers may submit a timely written request for an extension of time for Sayers or the Sayers Entity to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after the Sayers or the Sayers Entity fails to meet the revised deadline as agreed to by the OIG-approved extension.

Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after the Sayers receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Sayers or a Sayers Entity has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties to this CIA agree that a material breach of this CIA by Sayers or any Sayers Entity constitutes an independent basis for Sayers's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that Sayers and/or a Sayers Entity has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Sayers by certified mail of (a) Sayers's or the Sayers Entity's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

2. *Opportunity to Cure.* Sayers shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

- a. Sayers and/or the Sayers Entity is in full compliance with this CIA;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 35-day period, but that: (i) Sayers and/or the Sayers Entity has begun to take action to cure the material breach, (ii) Sayers and/or the Sayers Entity is pursuing such action with due diligence,

and (iii) Sayers and/or the Sayers Entity has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, Sayers fails to satisfy the requirement of section X.C.2, OIG may exclude Sayers from participation in the Federal health care programs. OIG will notify Sayers in writing of its determination to exclude Sayers (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Sayers is excluded under the provisions of this CIA, Sayers may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Material Breach.* A material breach of this CIA means:

- a. Failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D;
- b. Repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;
- c. Failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or
- d. Failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to Sayers of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Sayers shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this CIA shall be (a) whether Sayers or the Sayers Entity was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Sayers shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders Sayers to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Sayers may request review of the ALJ decision by the DAB.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be (a) whether Sayers or the Sayers Entity was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach could not have been cured within the 35 day period, but that (i) Sayers or the Sayers Entity has begun to take action to cure the material breach, (ii) Sayers or the Sayers Entity is pursuing such action with due diligence, and (iii) Sayers has provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. Sayers's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Sayers upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Sayers may request review of the ALJ decision by the DAB.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and Sayers agree to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Sayers and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns and transferees of Sayers;

EXHIBIT A

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

D. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

EXHIBIT A

ON BEHALF OF TERESITA SAYERS

Teresita Sayers
Teresita Sayers

3/3/99
DATE

EXHIBIT A

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



LEWIS MORRIS

Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

3/12/99
DATE